Attorney Docket No: 2006636-0050 IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Sulayman DIB-HAJJ et Examiner: Michael PAK

al.

Serial No.: 09/856,274 Art Unit: 1646 Filing Date: May 18, 2001 Confirmation No.: 5193

Title: Effects of GDNF and NGF on Sodium Channels in DRG Neurons

Mail Stop Petition Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

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Madam:

PETITION TO WITHDRAW FINALITY AND/OR REQUEST FOR PROPER ACTION

Applicants hereby respectfully request that finality of the Office Action mailed on December 29, 2008 be withdrawn and/or that a new Office Action be issued that substantively addresses Applicants' arguments.

Section 707.07(f) of the Manual of Patent Examining Procedure ("MPEP") provides, among other things, that "Where the applicant traverses any rejection, the examiner should, if he or she repeats the rejection, take note of the applicant's argument and answer the substance of it." In the present case, Applicant submitted arguments in a Response to Office Action dated September 17, 2008. The Examiner subsequently issued a Final Office Action that repeated the rejection levied in the prior Office Action yet provided no substantive response to the vast majority of Applicants' arguments.

The bulk of the final Office Action repeats the Examiner's summary of the same five references (Lin *et al.*, Yan *et al.*, Williams *et al.*, Mayer *et al.*, and Holstege *et al.*) cited in the previous Office Action (mailed March 17, 2008).

The Examiner's response to the Applicants' arguments is limited to a single assertion that "it is... clear that some or most of the neuropathic or nerve damaged patients suffer from pain." (page 5, Office Action). This assertion appears to be an attempt to address the Applicants' point that the Lin *et al.* reference must necessarily include administration of GDNF to a subject suffering from pain to meet a required claim limitation.

The Examiner has not responded to any of Applicants' other arguments in the response filed September 17, 2008. Specifically, Applicants have also argued that:

- 1) None of the references teach or suggest administering amounts of GDNF effective to alleviate pain.
- 2) Williams *et al.* does not teach or suggest administering GDNF to a human suffering from pain.
- 3) Mayer *et al.* does not teach what the Examiner claims it teaches. Mayer *et al.* only *speculates* that neuropathic pain is caused by damage to peripheral nerves.
- 4) Holstege *et al.* does not teach what the Examiner claims. Holstege *et al.* merely *speculates* that GDNF *may* be involved in nociception.
- 5) The fact pattern established by the references is exactly the *inverse* of the fact pattern that the Examiner attempts to show to establish a basis for the rejection.
- 6) None of the references, alone or in combination, teach or suggest that the administered GDNF alters tetrodotoxin-resistant sodium ion current in neuronal cells, a required claim limitation.

The Examiner has not provided any substantive response to any of these points. Applicants respectfully submit that examination cannot progress if the Examiner does not articulate the basis for any disagreement with a submitted argument. In light of the incompleteness of the Examiner's answer to Applicants' arguments, Applicant respectfully submits that the Finality of the Office Action mailed on December 29, 2008 was premature, and respectfully requests its withdrawal.

At a minimum, Applicant respectfully requests that any further Action from the Examiner respond in full to the substance of Applicant's presented arguments.

Applicant is concurrently submitting a Notice of Appeal.

Respectfully submitted,

Dated: March 30, 2009

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